



MAR 17 1998

Food and Drug Administration
Washington DC 20204

Rec'd 3/26/98 jb

Mr. Tod Kimbell
• Senior Research Director
PhysioLogics
6565 Odell Place
Boulder, Colorado 80301-3330

Dear Mr. Kimbell:

This is in response to your letter of January 5, 1998 to the Food and Drug Administration (FDA) pursuant to 21 USC 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the act)). Your submission states that PhysioLogics is making the following claims, among others, for the following products:

PhysioLogics Cranberry

“...shown to help inhibit some types of bacteria from adhering to the cells that line the urinary tract”

PhysioLogics Immunene

“...nutritionally support the body's immune system. This support is very helpful when the body is exposed to bacteria, viruses or other unfriendly microorganisms”

PhysioLogics DiaBest

“...nutritionally supports the specialized health needs of diabetics”

21 USC 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statements that you are making for these products suggest that they are intended to treat, prevent, cure, or mitigate disease, namely, urinary tract infections caused by the adhesion of pathogenic microorganisms and other infectious diseases. Because the adhesion to the bladder wall of non-pathogenic strains of microorganisms and the exposure of the body to nonpathogens would not result in disease, only the inhibition of adhesion of pathogenic strains of microorganisms or stimulating the body's response to pathogen exposure would be expected to contribute positively to the health of the person using these products. Additionally, the claims made for the product “DiaBest” suggest that it is intended to treat or mitigate diabetes. The claims made for these products do not meet the requirements of 21 USC 343(r)(6).

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343(r)(6). These claims suggest that these products are intended for use as drugs within the meaning of 21 USC 321(g)(1)(B), and that they are subject to regulation under the drug provisions of the act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855.

Please contact us if we may be of further assistance.

Sincerely,

James T. Tanner, Ph.D.
Acting Director
Division of Programs and Enforcement Policy
Office of Special Nutritionals
Center for Food Safety
and Applied Nutrition

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of
Enforcement, HFC-200
FDA, Denver District Office, Office of Compliance, HFR-SW240

cc:

HFA-224 (w/incoming)
HFA-305 (docket 97S-0163)
HFS-22 (CCO, JGordon)
HFS-456 (File)
HFS-450 (file, r/f)
HFD-310 (BWilliams)
HFD-314 (Aronson)
HFS-600 (Reynolds)
HFS-605 (Bowers)
GCF-1 (Nickerson, Dorsey)
r/d:HFS-456:RMoore:3/4/98
init:GCF-1:DDorsey:3/6/98
f/t:HFS-456:rjm:3/11/98:docname:57211.adv:disc26

FEB 18 1998

January 5, 1998


PhysioLogics®

6565 Odell Place

Boulder, CO

80301-3330

800-765-6775

303-530-4554

FAX 303-530-2592

Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C Street, SW
Washington, DC 20204

NOTIFICATION OF STATEMENTS
OF NUTRITIONAL SUPPORT

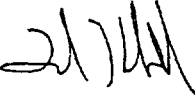
This Notification is filed pursuant to §403(r)(6) of the Federal Food Drug and Cosmetic Act (FDC Act), 21 U.S.C. §343(r)(6).

Name of dietary supplement: PhysioLogics Cranberry +

Statement(s) of
nutritional support:

Nutritional Support for the Urinary Tract
... shown to help inhibit some types of bacteria from adhering to the cells that
line the urinary tract.

I certify that the information contained in this notice is complete and accurate, and that we have substantiation that the statement(s) is (are) truthful and not misleading.



Tod Kimbell
Senior Research Director

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This Notification is filed pursuant to §403(r)(6) of the Federal Food Drug and Cosmetic Act (FDC Act), 21 U.S.C. §343(r)(6).

Name of dietary supplement: PhysioLogics DiaBest™

Statement(s) of
nutritional support: Nutritional Support for Diabetics
... nutritionally supports the specialized health needs of diabetics

I certify that the information contained in this notice is complete and accurate, and that we have substantiation that the statement[s] is [are] truthful and not misleading.



Tod Kimbell
Senior Research Director

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Name of dietary supplement: PhysioLogics Immunene®

Statement(s) of
nutritional support:

To Support The Body's Immune System
... nutritionally support the body's immune system. This support is very helpful
when the body is exposed to bacteria, viruses or other unfriendly
microorganisms.

I certify that the information contained in this notice is complete and accurate, and that we have substantiation that the statement[s] is [are] truthful and not misleading.

Tod Kimbell
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